Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Currently Amended) Construct for transdermal delivery of at least one immunogen to an individual comprising

a) said at least one immunogen, or at least one expressible nucleic acid encoding said immunogen

b) an occlusion vehicle and

c) an immunogen delivery system comprising:

i) at least one cationic sterol, and

ii) at least one saponin,

wherein said saponin forms a complex with said cationic sterol, and wherein said complex adopts a micro-particle structure in the form of a rigid cage-like matrix; wherein, if the construct comprises said nucleic acid, said cationic sterol or said saponin interacts electrostatically or hydrophobically with said nucleic acid.

2. (Previously presented) Construct according to claim 1, wherein the occlusion vehicle is a pressure sensitive adhesive.

3. (Cancelled)

4. (Previously Presented) Construct according to claim 1, wherein said construct is adapted for delivery through a skin surface or through a mucous membrane tissue.

5. (Previously presented) Construct according to claim 1, wherein the occlusion vehicle is an absorbing pressure sensitive adhesive.

6. (Previously Presented) Construct according to claim 1, wherein the occlusion vehicle is a hydrocolloid adhesive.

7. (Previously Presented) Construct according to claim 1, wherein the occlusion vehicle is a hydrogel adhesive.

8. (Previously Presented) Construct according to claim 1, wherein the occlusion vehicle is a cross-linked hydrogel adhesive.

9. (Previously Presented) Construct according to claim 1, wherein the immunogen and the immunogen delivery system are distributed homogenously in the occlusion vehicle.

10. (Previously Presented) Construct according to claim 1, wherein the immunogen and the immunogen delivery system are distributed on the surface of the occlusion vehicle.

11. (Cancelled).

12. (Cancelled).

13. (Previously presented) Construct according to claim 1, wherein the occlusion vehicle is a covering.

14. (Cancelled).

15. (Cancelled).

16. (Previously presented) Construct according to claim 1 further comprising a delivery rate controlling membrane.

17. (Previously presented) Construct according to claim 1, wherein the immunogen and the immunogen delivery system are separated from each other.

18. (Previously Presented) Construct according to claim 1 further comprising an enhancer for transdermal drug delivery.

19. (Cancelled)

20. (Previously Presented) Construct according to claim 1, wherein at least one immunogen is derived from a microorganism.

21. (Previously Presented) Construct according to claim 1, wherein at least one immunogen is derived from a virus.

22. (Cancelled)

23. (Previously presented) Construct according to claim 1, wherein the at least one immunogen is an immunogen which, when administered in an effective amount to a subject, elicits an immune response which is protective against the pathogenic microorganism with which that immunogen is associated.

24. (Cancelled)

25. (Previously Presented) Construct according to claim 20, wherein the at least one immunogen is selected in such a way that the induced immunological response is directed against a pathogenic component produced by said pathogenic microorganism during infection of said individual.

26. (Previously Presented) Construct according claim 1, wherein the immunogen comprises

i) one or more identical or different polypeptides and/or peptides,
ii) one or more identical or different lipopeptides,
iii) one or more identical or different nucleic acid sequence or sequences, which may encode polypeptides and/or peptides, or
iv) one or more identical or different polysaccharides and/or oligosaccharides,

or combinations thereof.

27. (Previously presented) Construct according to claim 1, wherein the immunogen and the immunogen delivery system are comprised within a vaccine formulation.

28. (Cancelled)

29. (Withdrawn) Process for the preparation of a construct according to claim 1, comprising the steps of introducing the immunogen and the immunogen delivery system, which are optionally comprised within a vaccine formulation, into the matrix of the occlusion vehicle or on its surface by dispersion or soaking in a solution of the vehicle or by applying to its surface, and optionally sterilising and/or drying and/or seal packaging the construct.

30. (Withdrawn) Process according to claim 29 further comprising the step of drying or lyophilisation or the immunogen and the immunogen delivery system before introducing into the vehicle.

31. (Withdrawn) Process according to claim 29 further comprising the step of adding one or more enhancers for transdermal drug delivery and/or one or more plasticizers.

32. (Previously Presented) Construct according claim 1, having one or more compartments.

33. (Previously Presented) Construct according to claim 32 having at least two compartments, wherein a first compartment comprises a lyophilised pad comprising the immunogen and the immunogen delivery system and a second compartment contains a solvent/diluent.

34. (Previously presented) Construct according to claim 1 comprising at least two separate compartments.

35. (Withdrawn) Method for generating an immunological response in an individual wherein said individual is treated transdermally with a construct according to any of the claims 1 to 28.

36. (Withdrawn) Method for treating or preventing a condition of illness in an individual, wherein said individual is treated transdermally with a construct according to any of the claims 1 to 28.

37. (Withdrawn) Method for vaccination of an individual wherein said individual is treated transdermally with a construct according to any of the claims 1 to 28.

38. (Previously Presented) The construct of claim 13 wherein the covering is a pad, patch or dressing.

39. (Previously Presented) The construct of claim 18 wherein the enhancer is selected from the group consisting of alcohols, amines, phospholipids, fatty acids, surfactants and polyols.

40. (Previously Presented) The construct of claim 20 wherein the microorganism is a bacterium selected from the group consisting of Achromobacter xylosoxidans, Acinetobacter calcoaceticus, Acinetobacter anitratus, Acinetobacter haemolyticus, Acinetobacter alcaligenes, Acinetobacter Iwoffii, Actinomyces israelii, Aeromonas hydrophilia, Aeromonas faecalis, Aeromonas odorans, Aeromonas denitrificans, Arizona hinshawii, Bacillus anthracis, Bacillus cereus, Bacteroides fragilis, Bacteroides melaninogenicus, Bordetella pertussis, Borrelia burgdorferi, Borrelia recurrentis, Brucella abortus, Brucella suis, Brucella melitensis, Brucella canis, Calymmatobacterium granulomatis, Campylobacter fetus ssp. intestinalis, Campylobacter fetus ssp. jejuni, Chlamydia psittaci, Chlamydia trachomatis, Chromobacterium violaceum, Citrobacter freundii, Citrobacter diversus, Clostridiurn botulinum, Clostridium perfringens, Clostridium difficile, Clostridium tetani, Corynebacterium diphtheriae, Corynebacterium ulcerans, Corynebacterium haemolyticum, Corynebacterium pseudotuberculosis, Coxiella burnetii, Edwardsiella tarda, Eikenella corrodens, Enterobacter cloacae, Enterobacter aerogenes, C. hafniae (also named Hafnia alvei) Enterobacter agglomerans, Erysipelothrix rhusiopathiae, Escherichia coli, Flavobacterium meningosepticum, Francisella tularensis, Fusobacterium nucleatum, Gardnerella vaginalis, Haemophilus ducreyi, Haemophilus

influenzae, Helicobacter species, Klebsiella pneumoniae, Klebsiella ozaenae, Klebsiella rhinoscleromatis, Legionella species, Leptospira interrogans, Listeria monocytogenes, Moraxella lacunata, Moraxella osloerisis, Mycobacterioum bovis, Mycobacterium leprae, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Neisseria gonorrhoeae, Neisseria meningitidis, Nocardia asteroides, Nocardia brasiliensis, Pasterurella haemolytica, Pasteurella multocida, Peptococcus magnus, Plesiomonas shigelloides, Pneumococci, Proteus mirabilis, Proteus vulgaris, Proteus rettgeri, Proteus morganii (also named Providencia rettgeri and Morganella morganii respectively), Providencia alcalifaciens, Providencia stuartii, Providencia rettgeri (also named Proteus rettgeri), Pseudomonas aeruginosa, Pseudomonas mallei, Pseudomonas pseudomallei, Rickettsia, Rochalimaia henselae, Salmonella enteridis, Salmonella typhi, Salmonella derby, Serratia marcescens, Shigella dysenteriae, Shigella flexneri, Shigella boydii, Shigella sonnei, Spirillum minor, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus saprophyticus, Streptobacillus moniliformis, Streptococcus faecalis, Streptococcus faecium, Streptococcus durans, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes, Treponema carateum, Treponeam pallidum, Treponema pertenue, Treponema pallidum, Ureaplasma urealyticum, Vibrio cholerae, Vibrio parahaemolyticus, Yersinia enterocolitica, and Yersinia pestis, or a parasite selected from the group consisting of Plasmodium species, Schistosomes, Trypanosomes, Leishmania, Filarial nematodes, Trichomoniasis, Sarcosporidiasis, Taenia Leishmania, Toxoplasma gondii, Trichinella spiralis, and Eimeria species, or a fungus selected from the group consisting of Cryptococcus neoformans, Candida albicans, Apergillus fumigatus and fungi causing Coccidioidomycosis.

41. (Previously Presented) The construct of claim 21 wherein the virus is selected from the group consisting of Adeno-associated virus, Adenovirus, Avian infectious bronchitis virus, Baculovirus, Chicken pox, Monkey Pox, Avi Pox, Corona virus, Cytomegalovirus, Distemper, Enterovirus, Epstein Barr virus, Feline leukemia virus, Flavivirus, Foot and mouth disease virus, Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis E, Herpes species, Herpes simplex, Influenza virus, HIV-l, HIV-2, HTLV I, Influenza A and B, Kunjin virus, Lassa fever virus, LCMV (lymphocytic choriomeningitis virus)/lentivirus,

Measles, Mengo virus, Morbillivirus, Myxovirus, Papilloma virus, Parovirus, Parainfluenza virus, Paramyxovirus, Parvovirus, Poko virus, Polio virus/Polyoma tumour virus, pseudorabies, Rabies virus, Reovirus, Respiratory syncytial virus, retrovirus, rhinovirus, Rinderpest, Rotavirus, Semliki forest virus, Sendai virus, Simian Virus 40, Sindbis virus, SV5, Tick borne encephalitis virus, Togavirus (rubella, yellow fever, dengue fever), Vaccinia virus, Venezuelan equine encephalomyelitis and Vesicular stomatis virus.

42. (Previously Presented) The construct of claim 36 wherein the condition is a disease caused by infection of said individual with a pathogenic microorganism.

43. (Cancelled)

44. (Previously presented) The construct of claim 26 wherein the immunogen comprises a peptide.

45. (Previously presented) The construct of claim 26 wherein the immunogen comprises a lipopeptide.

46. (Previously Presented) The construct of claim 1 which comprises an expressible nucleic acid encoding a peptide immunogen, which nucleic acid, after being delivered to said individual, is expressed, by cells of said individual, thereby delivering said peptide immunogen to said individual.

47. (Previously Presented) The construct of claim 46, wherein said nucleic acid encodes an immunogen capable of eliciting a protective immune response against a pathogenic microorganism.

48. (Previously Presented) The construct of claim 1 wherein at least one cationic sterol is DC-cholesterol.

49. (Previously Presented) The construct of claim 1 which further comprises at least one anionic or non-ionic sterol.

50. (Previously presented) The construct of claim 49 wherein the non-ionic sterol comprises cholesterol.

51. (Previously Presented) The construct of claim 48 which further comprises cholesterol.

52. (Previously Presented) The construct of claim 51 which further comprises phosphatidylcholine.

53. (Previously presented) The construct of claim 1 wherein the saponin comprises Quil A.

54. (Previously presented) The construct of claim 1 wherein said immunogen comprises tetanus toxoid.

55. (Previously presented) The construct of claim 1, wherein said immunogen comprises Hepatitis B surface antigen.

56. (Previously presented) The construct of claim 1, in which the complex is in the form of microparticles with an average diameter of about 5 to 50 nm.

57. (Cancelled)

58. (Cancelled)

59. (Cancelled)

60. (Previously Presented) The construct of claim 1 wherein the immunogen comprises one or more saccharide units.

61. (Previously presented) The construct of claim 18, wherein the enhancer is low MW-polyethylene glycol, propylene glycol, lauric acid, oleic acid, methyl laurate, ethyl oleate, N-methylpyrrolidone, dioctyl adipate or glycerol.